EXHIBIT A

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RESPONSES AND OBJECTIONS TO PLAINTIFFS' NOTICES OF 30(b)(6) DEPOSITION OF DEFENDANTS

Defendants Ethicon, Inc. ("Ethicon") and Johnson & Johnson ("J&J") (collectively, "Defendants") hereby respond and object to Plaintiffs' "Amended Notice to Take Oral Deposition of Defendant Through Designated Witness Regarding TVT-O" (Doc. 482); Plaintiffs' "Amended Notice to Take Oral Deposition of Defendant Through Designated Witness Regarding TVT-A" (Doc. 484); Plaintiffs' "Amended Notice to Take Oral Deposition of Defendant Through Designated Witness Regarding TVT-CLASSIC" (Doc. 485); Plaintiffs' "Amended Notice to Take Oral Deposition of Defendant Through Designated Witness Regarding TVT-S" (Doc. 486); and Plaintiffs' "Amended Notice to Take Oral Deposition of Defendant Through Designated Witness Regarding TVT-E" (Doc. 491) (collectively, the "Notices") which were served on April 2 and 3, 2013..

The Notices are attached as Exhibit "A." They purport to identify the areas in which Defendants' representatives will testify at deposition and relate to seven devices manufactured by Ethicon: TVT (including TVT-AA and TVT-D); TVT-Obturator ("TVT-O"); TVT-Secur; TVT Exact; and TVT Abbrevo (collectively, the "Devices"). More specifically, the Notices pertain to the design and development of the Devices and are identical in all respects other than the specific device at issue. In the interest of expediency and efficiency, Defendants collectively respond herein to each of the Notices.[1]

The responses and objections contained herein are made without in any way waiving or intending to waive—but on the contrary reserving and intending to reserve—the right at any time to revise, supplement, correct, or add to these objections and responses. Defendants note that no documents have been withheld from production on the basis of the objections set forth in this Response unless expressly stated.

SPECIFIC RESPONSES AND OBJECTIONS TO THE NOTICES

Topic a: The Standard Operating Procedures (SOP) associated with design and development of the Devices.

Response and Objections to Topic a: Federal Rule of Civil Procedure 30(b)(6) requires that the deposition notice "describe with reasonable particularity the matters for examination." The purpose of this requirement is to permit the deponent to be able to prepare properly for the deposition, as the deponent may be asked to testify on matters outside of his or her personal knowledge. Defendants object that this topic is overbroad and unduly burdensome and provides insufficient notice under Rule 30(b)(6). The design and development of the Devices were long

[1] Inasmuch as each of the Notices relates to a single device, the topics set forth therein reference the particular device at issue. For example, in the Notice regarding TVT-O, the first topic is the "Standard Operating Procedures (SOP) associated with design and development of TVT-O." Each of the other four Notices is identical, but references one of the other devices. In responding and/or objecting to the Notices' topics, Defendants will refer generally to the Devices rather than to any specific device.

term projects, taking a total of more than a dozen years from TVT to TVT Exact and Abbrevo. Thus, the Standard Operating Procedures associated with each device were revised multiple times over the course of this time period. Defendants object that: (a) it is impossible for any witness to testify about every version of the Standard Operating Procedure associated with each device; (b) this topic is overbroad since there will be numerous standard operating procedures applicable to the design of the Devices that have no bearing on this litigation; and (c) this is an improper topic for an oral deposition as this information can be more efficiently transmitted by a document production regarding the particular standard operating procedures that Plaintiffs seek to discover.

Subject to and without waiving these Specific Objections, Defendants will produce a witness or witnesses whose testimony will address the most recent Standard Operating Procedure associated with the design and development of the Devices and answer questions to the best of his or her ability regarding this improper request.

Topic b: The complete design history file for the Devices, including each component part of the file, the custodian responsible for the file and the maintenance of the file.

Response and Objections to Topic b: During a meet and confer held on March 22, 2013, and in correspondence exchanged prior to that meet and confer, Defendants objected that this topic is overbroad, is not stated with reasonable particularity as required by the Rule, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). It is Defendants' understanding that, as a result of that meet and confer, Plaintiffs agreed that this topic is overly broad and reformulated it to seek testimony regarding the following: (1) what makes up the

Design History File ("DHF"); (2) what are the component parts of the DHF; (3) the custodian of the DHF; (4) how the DHF is maintained; and (5) the Bates ranges for each DHF.

Defendants will produce a witness to testify in regard to items 1-4 of the reformulated topic. But Defendants object that item 5 is an inappropriate subject for a 30(b)(6) deposition. Each of the products at issue has a design history file. These design history files are voluminous and, in total, comprise more than ten thousand pages of material. Due to the size of these documents, no company witness could possibly testify to the completeness of a particular DHF presented to him or her. Moreover, the individual whom Defendants will designate regarding the topic of DHFs played no role in Bates stamping these documents and cannot personally verify the accuracy of any produced copy.

Defendants are more than willing to provide Plaintiffs a written discovery response that identifies the Bates ranges of each DHF to satisfy any concern Plaintiffs may have about the completeness of the DHFs produced.

Topic c: Members and procedures of the Product Development Team for the Devices.

Responses and Objections to Topic c: Defendants object that this topic is overbroad and unduly burdensome and provides insufficient notice under Rule 30(b)(6). The design and development of the Devices were long-term projects; the members and procedures of the Product Development Team for the Devices changed over time encompassing more than twelve years; and this information is reflected in the design history files—which encompass more than ten thousand pages of material. It is impossible for any witness to testify about the members and procedures of the Product Development Team for seven products. Defendants further object that this topic is vague and ambiguous. Due to the long-term nature of the projects, as well as the fact that many individuals played only a tangential role in those projects, various witnesses may consider the same individual to be "on" or "not on" the design team for a particular device. Finally, Defendants object that the information sought in this topic is more readily available to Plaintiffs from other sources. Such information is included in the design history files, which Defendants have already produced to Plaintiffs as they were kept in the ordinary course of business and in an electronically searchable format. *See, e.g.*, *Catt v. Affirmative Ins. Co.*, No. 2:09-CV-243, 2009 WL 1228605 at * (N.D. Ind. Apr. 30, 2009) (finding deposition topic that sought general testimony about documents produced "too broad and not described with reasonable particularity").

As part of the meet and confer process, Defendants identified specific documents (such as the Design and Development Plan, Team meeting minutes, and lab reports) that list individuals working on the projects. As a result, Plaintiffs can ascertain the identities of the individuals who worked on these projects without undue burden.

Topic d: The Operating Procedures associated with Product Development Cycle.

Responses and Objections to Topic d: Defense counsel do not understand what is sought by this topic. If Plaintiffs clarify this topic, subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic e: The Design Output file, including the specifications of the Devices.

Responses and Objections to Topic e: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic f: The user needs and design requirements for the Devices.

Responses and Objections to Topic f: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic g: The Cadaver Lab evaluations for the Devices.

Responses and Objections to Topic g: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic h: The specifics of all testing related to the Devices during the design and development stages, including but not limited to bench testing, porosity testing, particle loss, fraying, degradation, and leaching.

Responses and Objections to Topic h: Defendants object that: (a) it would be impossible for any witness (or even multiple witnesses) to testify regarding the "specifics of all testing related to the Devices;" (b) this topic is overbroad since there are numerous tests performed on the Devices that have no bearing on this litigation; and (c) this is an improper topic for an oral deposition as this information can be more efficiently transmitted by a document production regarding the particular tests Plaintiffs seek to discover.

Subject to and without waiving these Objections, Defendants will produce witnesses who will be prepared to address the testing to the best of their ability. This will require the designation of several different individuals; Defendants disclosed the identity of those individuals by correspondence to Plaintiffs' counsel dated March 28, 2013.

Topic i: All project names of the Devices.

Responses and Objections to Topic i: Defendants object that the information sought in this topic is more readily available to Plaintiffs from other sources. Such information is included in the design history files, which Defendants have already produced to Plaintiffs in the manner they were kept in the ordinary course of business and in an electronically searchable format. *See, e.g.*, *Catt v. Affirmative Ins. Co.*, No. 2:09-CV-243, 2009 WL 1228605 at * (N.D. Ind. Apr. 30, 2009) (finding deposition topic that sought general testimony about documents produced "too broad and not described with reasonable particularity").

In an effort to compromise, Defendants will, in advance of the deposition, provide Plaintiffs with a list of the project names it has identified for the Devices to date.

Topic j: Design verification of the Devices.

Responses and Objections to Topic j: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic k: Design validation of the Devices.

Responses and Objections to Topic k: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic l: The Design Review, Process Qualification (PQ) and Design Transfer for the Devices.

Responses and Objections to Topic l: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic m: The Product Device Design Safety Assessment (DDSA) and the policies and procedures related to these analyses.

Responses and Objections to Topic m: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic n: Product Device Design Failure Modes Effects Analysis (dFMEA), Process Failure Modes Effects Analysis (pFMEA) and Application Failure Modes Effects Analysis (aFMEA).

Responses and Objections to Topic n: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic o: The Product Device Design Requirements Matrix.

Responses and Objections to Topic o: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic p: The Product Device Qualitative and Quantitative Characteristics Worksheets, including but not limited to Hazard Worksheet and ranking tables.

Responses and Objections to Topic p: Defendants object that this topic overlaps with several prior topics (in particular topics m and n), and any intended differentiation between this topic and prior topics is vague and ambiguous.

Defendants invite Plaintiffs to meet and confer to determine whether there is any aspect of this topic that is not already being addressed by testimony that Defendants have agreed to provide in response to prior topics.

Topic q: The Clinical Validation Test Reports; Procedures for preparing and keeping Minutes and Agendas for Design Review Meetings.

Responses and Objections to Topic q: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic r: As it relates to design control and validation, any and all discussions or documents related to whether or not to design, develop, coordinate, create, participate in and/or fund any clinical registries regarding the Devices.

Responses and Objections to Topic r: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic s: Any patents related to the Devices and their predecessor mesh products.

Responses and Objections to Topic s: As a result of the parties' meet and confer held on March 22, 2013, Plaintiffs agreed to limit this topic to the Devices identified in the Notices (i.e., TVT, TVT-AA, TVT-O, TVT-Secur, TVT Exact, and TVT-Abbrevo). Additionally, during that same meet and confer and in response to Defendants' objection that the topic was too broad, Plaintiffs indicated that their areas of interest were the identity of the inventor, the name of the patent holder, a description of the patent, and testimony regarding the patents for the Devices from a "design perspective."

Defendants maintain their objection that this topic, as limited by Plaintiffs, fails to describe with reasonable particularity the matters for examination, as required by Rule 30(b)(6). In an effort to compromise, however, Defendants will produce a witness to testify about the United States patents directly related to the Devices. For each of these patents, Defendants' designee will be prepared to testify as a corporate representative regarding the identity of the inventor, the name of the present holder of each patent, and the patent's description. Additionally, the designee will be prepared to testify about the patents from a "design perspective" and to his or her personal knowledge concerning each of the patents at issue.

Finally, Defendants note that the Devices are the subject of patent filings in ex-United States jurisdictions. Defendants do not read the Notices to seek testimony concerning ex-United States patents. To the extent the Notices do seek such testimony, Defendants object to the production of any information regarding ex-United States patents (or patent filings) as not reasonably calculated to lead to the discovery of admissible evidence, unreasonably burdensome, and equally available to Plaintiffs, to the extent such filings are matters of public record.

Topic t: The identity of and financial compensation paid to any consultants retained during the design and development of the Devices.

Responses and Objections to Topic t: Defendants object that this topic is vague and ambiguous, overbroad, and unduly burdensome and provides insufficient notice under Rule 30(b)(6).

As an initial matter, the topic refers to the identity of "any consultants" and does not limit itself to consultants who participated in the design of the Devices. Additionally, even if the topic is read to request testimony only on the consultants who participated in the design and development of the Devices, these Devices were designed over a period of more than a dozen years and involve seven products. No witness could be prepared to testify on this topic.

Subject to and without waiving any objections, Defendants are still making inquiries regarding this proposed topic.

Topic u: The monitoring, investigation and evaluation of post-marketing adverse event reports for the Devices for design issues.

Responses and Objections to Topic u: Subject to and without waiving any objections, Defendants designated Dan Lamont on this topic which was addressed at his deposition on April 3 and 4, 2013.

Topic v: The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding the Devices for design issues.

Responses and Objections to Topic v: Subject to and without waiving any objections, Defendants are still making inquiries regarding this proposed topic.

Topic w: As it relates to design control and validation, the investigation, evaluation and determination as to whether there is an association between the design of the Devices and any adverse event experienced by patients who were provided the Devices.

Responses and Objections to Topic w: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic x: The investigation, evaluation and determination as to whether there is a causal connection between the design of the Devices and any adverse event or injuries.

Responses and Objections to Topic x: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic y: The substantive design and approval of package inserts, IFUs, and other labeling for the Devices (both U.S. and foreign), including the specific dates of use for each such items and any design changes thereto.

Responses and Objections to Topic y: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic as it relates to the English language to the extent such information is reasonably available to Defendants. To the extent it relates to foreign labeling, Defendants object that this topic fails to meet the particularity requirement of Rule 30(b)(6). No witness could be prepared to testify about the labeling in all languages for the Devices. Moreover, Defendants object that the topic is not reasonably calculated to the discovery of admissible evidence, unless Plaintiffs can establish that the implanting surgeons in this case relied on non-English versions of Defendants' labels. Finally, Defendants object that assembling such information would be unduly burdensome. If the Plaintiffs believe that a particular IFU in a particular language other than English is relevant to this case, Defendants invite them to meet and confer on this issue.

Topic ii (sic): The maintenance of Ethicon Inc.'s finances, budgets and expenditures with regard to design and development related to the Devices from the date first started developing the Devices until the present.

Responses and Objections to Topic ii: Defendants object that this topic is vague and ambiguous, in particular as to the phrase "finances . . . with regard to design and development," and provides insufficient notice under Rule 30(b)(6). Defendants further object that this topic is overbroad and unduly burdensome, in that, as written, it seeks information regarding every single expenditure related to the design and development of seven products during a time period encompassing more than a dozen years. It is impossible for any witness to testify on every such expenditure.

Subject to and without waiving any objections, Defendants are still making inquiries regarding this proposed topic.

Topic jj (sic): The interaction and communication internally or with any outside consultants regarding the design specifications, including conformance to specifications of the Devices, from the date Ethicon, Inc. first started development the Devices until the present.

Responses and Objections to Topic jj: Defendants object that: (a) it is impossible for any witness (or even multiple witnesses) to testify regarding the "interaction and communication internally or with any outside consultants regarding the design specifications, including conformance to specifications of the Devices" since such communications and interaction would have occurred over the course of more than a dozen years; (b) this topic is dramatically overbroad since there will be numerous consultants and interactions related to the Devices that have no bearing on this litigation; and (c) this is an improper topic for an oral deposition as this information can be more efficiently transmitted by a document production regarding the particular communications Plaintiffs seek to discover.

Subject to and without waiving any objections, Defendants are still making inquiries regarding this proposed topic.

Topic kk (sic) As they relate to design control and validation, the manufacturing processes, including but not limited to heating/extrusion/annealing/cooling/gamma radiation/sterilization.

Responses and Objections to Topic kk: Defendants object that: (a) it is impossible for any witness (or even multiple witnesses) to testify regarding the "the "manufacturing processes" for all seven devices over a period of more than a dozen years; (b) this topic is dramatically overbroad since there will be numerous manufacturing processes related to the Devices that have no bearing on this litigation; and (c) this is an improper topic for an oral deposition as this information can be more efficiently transmitted by a document production regarding the particular communications Plaintiffs seek to discover.

In the meet and confer held on March 22, 2013, Plaintiffs advised Defendants that this topic seeks testimony regarding the process by which the Prolene mesh is manufactured, woven, tested, and sterilized, as well as similar "type" information regarding the tools that accompany each device. As explained during that meet and confer, Defendants will produce a witness or witnesses who are knowledgeable about the manufacturing processes in general and will be prepared to discuss this topic at a high level. To the extent Plaintiffs elect to drill down on a particular topic in greater detail, Defendants may have to identify additional witnesses to address those topics.

Topic z: The identity of the individuals involved the [sic] defendants' original decision to design, develop and manufacture the Devices.

Responses and Objections to Topic z: Defendants object that this topic is vague and ambiguous, in particular as to the phrase "original decision," and does not provide the reasonable particularity required by Rule 30(b)(6). Notwithstanding this objection, Defendants have agreed to present a witness to testify regarding this topic to the best of his or her ability, given the problems identified.

Topic aa: All medical assessments of the Devices as they relate to the design control and validation process.

Responses and Objections to Topic aa: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic bb: The specifics of all clinical, preclinical, and medical testing related to the Devices during the design and development stages.

Responses and Objections to Topic bb: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic cc: Animal Testing Records for Biocompatibility as part of the design of the Devices.

Responses and Objections to Topic cc: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Topic dd: The evaluation of data and results of any pre-clinical studies, clinical trials and testing regarding the Devices.

Responses and Objections to Topic dd: Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendants.

Document Request No. 1: All documents relied upon by the deponent in preparing for this deposition.

Responses and Objections to Document Request No. 1: Defendants object that this request seeks information protected by the attorney work product doctrine. *See, e.g.*, *Hickman v. Taylor*, 329 U.S. 495, 511 (1947); *In re Allen*, 106 F.3d 582, 608 (4th Cir. 1997) (observing that "choice and arrangement [of documents in witness's personnel file by counsel for witness] constitutes opinion work product because [counsel's] section and compilation of these particular documents reveals her thought processes and theories regarding this litigation"); *Rhodes v. E.I du Pont de Nemours & Co.*, 558 F. Supp. 2d 660, 671 (S.D. W. Va. 2008) (Goodwin, C.J.) ("Courts acknowledge that the document selection process represents the mental impressions of the party's counsel and is protected work product." (internal quotation marks and alterations omitted)). Defendants further note that each and every document relied upon by the deponent(s) in preparing for this deposition(s) has already been produced to Plaintiffs, and Defendants object to Plaintiffs' request to replicate that production.

Document Request No. 2: Two exemplar products for all products listed in the Device definitions.

Responses and Objections to Document Request No. 2: Defendants have previously produced to Plaintiffs an exemplar of each product at issue. Because there is no obligation under the Federal Rules of Civil Procedure to produce multiple product samples of the products at issue, Defendants object to this request and are not producing additional exemplars at this time. If Plaintiffs have a compelling reason that they need multiple exemplars of one of the products at issue, Defendants invite them to meet and confer on this issue.

Document Request No. 3: Prototype meshes and samples/pathology/histopathology slides of all pathology testing on the Devices.

Responses and Objections to Document Request No. 3: Defendants object that this request is overbroad and unduly burdensome and do not intend to produce such samples at this time. Defendants invite Plaintiffs to meet and confer to determine whether there are any particular prototypes and samples/pathology/histopathology slides Defendants can or should produce.

Document Request No. 4: All documents concerning corporate, departmental, and employee organizational charts for your design and development department, product development or product cycle teams.

Responses and Objections to Document Request No. 4: Defendants object that this request is overbroad and unduly burdensome, in that it includes no temporal limitation and is not limited to the Devices. Without waiving this objection, Defendants have produced organizational charts for Ethicon. These charts were produced at the following Bates ranges:

ETH.MESH.00002221-ETH.MESH.00002548; and

ETH.MESH.00335088-ETH.MESH.00335617.

Document Request No. 5: The following documents for the design and development of the Devices, including but not limited to:

a. The Clinical Expert reports;

b. Each version of the Device Design Safety Assessment (DDSA's); Each version of the Design Failure Modes Effects Analysis (dFMEAs), Process Failure Modes

Effects Analysis (pFMEAs), Application Failure Modes Effects Analysis (aFMEA);

c. Operating Procedures for Failure Modes and Effects Analysis;

d. Operating Procedure for Device Design Safety Assessment;

e. Design history files;

f. Design and specification of equipment used in the production of the Devices;

g. Design and specifications of packaging used in the production of the Devices;

h. Specifications regarding sanitization and sterilization of the Devices, plant facilities and plant equipment;

i. Mesh Specifications;

j. Franchise procedure for medical device risk management plan;

k. Company procedure for medical device risk management plan;

l. Work Instruction for device risk management;

m. The Franchise procedure for the control and disposition of nonconforming product;

n. All company policies and procedures that apply to or relate to the Design History File;

o. The Franchise Procedure for Corrective and Preventative Action (CAPA) as well as any other company policies and procedures related to CAPAs;

p. Risk management plans and reports for the Devices;

q. Members of product development team(s);

r. Operating procedures associated with a product development cycle;

s. The Devices' quality manuals;

t. The Devices' quality plans;

u. Management responsibilities under a quality system;

v. Mesh product design review, design verification, process qualification and design transfer;

w. Mesh product device design requirements matrix;

x. Mesh product qualitative and quantitative characteristics worksheets, including but not limited to hazard worksheet raking (sic) tables;

y. Mesh product validation test reports; and

z. Mesh product biocompatibility testing records.

Responses and Objections to Document Request No. 5: Defendants object that this request is overbroad and unduly burdensome, in that many of its subparts include no temporal limitation and are not limited to the Devices. Defendants further object that the request is vague and ambiguous because, among other things, the term "Franchise Procedure" is undefined. Finally, Defendants object that certain of the documents sought in this request are more readily available to Plaintiffs from other sources. Defendants have, for example, already produced to Plaintiffs the complete design history files as they were kept in the ordinary course of business in an electronically searchable format. Without waiving these objections, below are the Bates ranges of previously produced documents that Defendants believe are responsive to each subpart of this request:

a. The Clinical Expert reports;

ETH.MESH.04384126-ETH.MESH.04384165
ETH.MESH.01189423-ETH.MESH.01189439
ETH.MESH.00222899-ETH.MESH.00222909
ETH.MESH.01269170-ETH.MESH.01269207
ETH.MESH.00352889-ETH.MESH.00352909
ETH.MESH.00353020-ETH.MESH.00353037
ETH.MESH.00353675-ETH.MESH.00353695
ETH.MESH.00581212-ETH.MESH.00581229
ETH.MESH.00603823-ETH.MESH.00603843
ETH.MESH.00826028-ETH.MESH.00826045
ETH.MESH.01211448-ETH.MESH.01211468
ETH.MESH.01268329-ETH.MESH.01268349
ETH.MESH.01417471-ETH.MESH.01417491
ETH.MESH.01752416-ETH.MESH.01752433
ETH.MESH.01795909-ETH.MESH.01795929

ETH.MESH.03032071-ETH.MESH.03032091
ETH.MESH.04548176-ETH.MESH.04548196

b. Each version of the Device Design Safety Assessment (DDSA's); Each version of the Design Failure Modes Effects Analysis (dFMEAs), Process Failure Modes Effects Analysis (pFMEAs), Application Failure Modes Effects Analysis (aFMEA);

ETH.MESH.01317510-ETH.MESH.01317512
ETH.MESH.00752937-ETH.MESH.00752937
ETH.MESH.01407852-ETH.MESH.01407852
ETH.MESH.06268141-ETH.MESH.06268143
ETH.MESH.06277080-ETH.MESH.06277080
ETH.MESH.00223177-ETH.MESH.00223186
ETH.MESH.00222389-ETH.MESH.00222392
ETH.MESH.00754859-ETH.MESH.00754859
ETH.MESH.01419741-ETH.MESH.01419741
ETH.MESH.01423057-ETH.MESH.01423057
ETH.MESH.05975526-ETH.MESH.05975526
ETH.MESH.00754439-ETH.MESH.00754440
ETH.MESH.00754497-ETH.MESH.00754498

c. Operating Procedures for Failure Modes and Effects Analysis;

ETH.MESH.03742801-ETH.MESH.03742835

d. Operating Procedure for Device Design Safety Assessment;

ETH.MESH.03742519-ETH.MESH.03742531
ETH.MESH.03742532-ETH.MESH.03742545

e. Design history files;

ETH.MESH.00218088-ETH.MESH.00218100
ETH.MESH.00221918-ETH.MESH.00221996
ETH.MESH.00223778-ETH.MESH.00223792
ETH.MESH.00748002-ETH.MESH.00748057
ETH.MESH.00748213-ETH.MESH.00748278
ETH.MESH.01309984-ETH.MESH.01310080
ETH.MESH.01310426-ETH.MESH.01310482
ETH.MESH.01316727-ETH.MESH.01317613
ETH.MESH.01589783-ETH.MESH.01589787
ETH.MESH.01589800-ETH.MESH.01589802
ETH.MESH.01589807-ETH.MESH.01589826
ETH.MESH.03878631-ETH.MESH.03878675
ETH.MESH.00223393-ETH.MESH.00223585

ETH.MESH.00752859-ETH.MESH.00753374
ETH.MESH.00759119-ETH.MESH.00759119
ETH.MESH.00759159-ETH.MESH.00759161
ETH.MESH.01407509-ETH.MESH.01592202
ETH.MESH.01592245-ETH.MESH.01594412
ETH.MESH.01594445-ETH.MESH.01594780
ETH.MESH.02312487-ETH.MESH.02312659
ETH.MESH.00748059-ETH.MESH.00748084
ETH.MESH.01310089-ETH.MESH.01310116
ETH.MESH.01589668-ETH.MESH.01589676
ETH.MESH.01589680-ETH.MESH.01589690
ETH.MESH.00221997-ETH.MESH.00222463
ETH.MESH.01317769-ETH.MESH.01318358
ETH.MESH.00222464-ETH.MESH.00222778
ETH.MESH.01318359-ETH.MESH.01318831
ETH.MESH.00222779-ETH.MESH.00223267
ETH.MESH.01318832-ETH.MESH.01319499
ETH.MESH.01319500-ETH.MESH.01320123
ETH.MESH.00073415-ETH.MESH.00073424
ETH.MESH.00223634-ETH.MESH.00223639
ETH.MESH.00223654-ETH.MESH.00223655
ETH.MESH.00223800-ETH.MESH.00223828
ETH.MESH.00340459-ETH.MESH.00340467
ETH.MESH.00341700-ETH.MESH.00341702
ETH.MESH.00341720-ETH.MESH.00341729
ETH.MESH.00599666-ETH.MESH.00599668
ETH.MESH.00754858-ETH.MESH.00755383
ETH.MESH.01223664-ETH.MESH.01223689
ETH.MESH.01419739-ETH.MESH.01423820
ETH.MESH.01590015-ETH.MESH.01592898
ETH.MESH.01593009-ETH.MESH.01593254
ETH.MESH.01593459-ETH.MESH.01593681
ETH.MESH.02313037-ETH.MESH.02312042
ETH.MESH.06105506-ETH.MESH.06015508
ETH.MESH.00223588-ETH.MESH.00223633
ETH.MESH.00223793-ETH.MESH.00223799
ETH.MESH.00754439-ETH.MESH.00754857
ETH.MESH.00759086-ETH.MESH.00759158
ETH.MESH.01320389-ETH.MESH.01320394
ETH.MESH.01413955-ETH.MESH.01419738
ETH.MESH.01589884-ETH.MESH.01590014
ETH.MESH.01591876-ETH.MESH.01591913
ETH.MESH.01592339-ETH.MESH.01592352
ETH.MESH.01592399-ETH.MESH.01592433
ETH.MESH.01592438-ETH.MESH.01592488

ETH.MESH.01592496-ETH.MESH.01592686
ETH.MESH.01592696-ETH.MESH.01592781
ETH.MESH.01592791-ETH.MESH.01592877
ETH.MESH.01592881-ETH.MESH.01593008
ETH.MESH.01593255-ETH.MESH.01593458
ETH.MESH.01594249-ETH.MESH.01594272
ETH.MESH.01594413-ETH.MESH.01594444
ETH.MESH.02312660-ETH.MESH.02313036
ETH.MESH.02604374-ETH.MESH.02604408
ETH.MESH.02615220-ETH.MESH.02615222

f. Design and specification of equipment used in the production of the Devices;

ETH.MESH.01317567-ETH.MESH.01317570
ETH.MESH.01409891-ETH.MESH.01410043
ETH.MESH.04974594-ETH.MESH.04974595
ETH.MESH.04974598-ETH.MESH.04974605
ETH.MESH.05795838-ETH.MESH.05795948
ETH.MESH.01420019-ETH.MESH.01420085
ETH.MESH.00755047-ETH.MESH.00755049
ETH.MESH.01420019-ETH.MESH.01420128
ETH.MESH.01422251-ETH.MESH.01422256
ETH.MESH.01422257-ETH.MESH.01422261
ETH.MESH.00754629-ETH.MESH.00754636
ETH.MESH.01414880-ETH.MESH.01415963
ETH.MESH.01592339-ETH.MESH.01592352
ETH.MESH.01592666-ETH.MESH.01592683
ETH.MESH.01592868-ETH.MESH.01592877
ETH.MESH.02010461-ETH.MESH.02010462

g. Design and specifications of packaging used in the production of the Devices;

ETH.MESH.01317529-ETH.MESH.01317530
ETH.MESH.00307955-ETH.MESH.00307958
ETH.MESH.00308614-ETH.MESH.00308615
ETH.MESH.00753322-ETH.MESH.00753325
ETH.MESH.01407738-ETH.MESH.01407745
ETH.MESH.01409238-ETH.MESH.01409240
ETH.MESH.01409489-ETH.MESH.01409490
ETH.MESH.01592079-ETH.MESH.01592088
ETH.MESH.05299418-ETH.MESH.05299418
ETH.MESH.06169520-ETH.MESH.06169529
ETH.MESH.00222581-ETH.MESH.00222581
ETH.MESH.00222640-ETH.MESH.00222668
ETH.MESH.00755207-ETH.MESH.00755211
ETH.MESH.01420322-ETH.MESH.01420338

ETH.MESH.01420346-ETH.MESH.01420358
ETH.MESH.01420372-ETH.MESH.01420375
ETH.MESH.01422558-ETH.MESH.01422559
ETH.MESH.01422793-ETH.MESH.01422827
ETH.MESH.01422887-ETH.MESH.01422890
ETH.MESH.00754686-ETH.MESH.00754688
ETH.MESH.01417492-ETH.MESH.01417596

h. Specifications regarding sanitization and sterilization of the Devices, plant facilities and plant equipment;

ETH.MESH.01317533-ETH.MESH.01317538
ETH.MESH.00752991-ETH.MESH.00753053
ETH.MESH.01407826-ETH.MESH.01407836
ETH.MESH.01409227-ETH.MESH.01409229
ETH.MESH.05796236-ETH.MESH.05796241
ETH.MESH.01318365-ETH.MESH.01318365
ETH.MESH.00755257-ETH.MESH.00755277
ETH.MESH.01423256-ETH.MESH.01423699
ETH.MESH.00754776-ETH.MESH.01418736

i. Mesh Specifications;

ETH.MESH.05224994-ETH.MESH.05224997
ETH.MESH.03358376-ETH.MESH.03358378
ETH.MESH.00308009-ETH.MESH.00308017
ETH.MESH.00308607-ETH.MESH.00308607
ETH.MESH.01407536-ETH.MESH.01407539
ETH.MESH.01410044-ETH.MESH.01410047
ETH.MESH.05299517-ETH.MESH.05299517
ETH.MESH.03715235-ETH.MESH.03715240
ETH.MESH.00755044-ETH.MESH.00755046
ETH.MESH.00755050-ETH.MESH.00755054
ETH.MESH.01422207-ETH.MESH.01422212
ETH.MESH.01422238-ETH.MESH.01422247
ETH.MESH.01422369-ETH.MESH.01422380
ETH.MESH.01422406-ETH.MESH.01422409
ETH.MESH.01422414-ETH.MESH.01422420
ETH.MESH.00754638-ETH.MESH.00754652
ETH.MESH.01416450-ETH.MESH.01416496

j. Franchise procedure for medical device risk management plan;

ETH.MESH.03742440-ETH.MESH.03742466

k. Company procedure for medical device risk management plan;

ETH.MESH.03742232-ETH.MESH.03742257

l. Work Instruction for device risk management;

ETH.MESH.03742546-ETH.MESH.03742570

m. The Franchise procedure for the control and disposition of nonconforming product;

ETH.MESH.03750311-ETH.MESH.03750351

n. All company policies and procedures that apply to or relate to the Design History File;

Defendants will continue to search to determine whether any documents responsive to this Request have been produced or should be produced and invite Plaintiffs to meet and confer on this issue.

o. The Franchise Procedure for Corrective and Preventative Action (CAPA) as well as any other company policies and procedures related to CAPAs;

ETH.MESH.03739016-ETH.MESH.03739034
ETH.MESH.03739119-ETH.MESH.03739156

p. Risk management plans and reports for the Devices;

ETH.MESH.00223779-ETH.MESH.00223784
ETH.MESH.00355500-ETH.MESH.00355516
ETH.MESH.01268264-ETH.MESH.01268277
ETH.MESH.01310061-ETH.MESH.01310065
ETH.MESH.01310476-ETH.MESH.01310481
ETH.MESH.01589812-ETH.MESH.01589825
ETH.MESH.04385327-ETH.MESH.04385340
ETH.MESH.00752928-ETH.MESH.00752932
ETH.MESH.00752940-ETH.MESH.00752943
ETH.MESH.00823952-ETH.MESH.00823954
ETH.MESH.03647572-ETH.MESH.03647580
ETH.MESH.00355500-ETH.MESH.00355516
ETH.MESH.01589812-ETH.MESH.01589825
ETH.MESH.00260076-ETH.MESH.00260085
ETH.MESH.01419796-ETH.MESH.01419805
ETH.MESH.01423223-ETH.MESH.01423227
ETH.MESH.01418539-ETH.MESH.01418544
ETH.MESH.01593315-ETH.MESH.01593325
ETH.MESH.04203368-ETH.MESH.04203375

q. Members of product development team(s);

The members of the product development teams are set forth in the Design History Files (see subpart (e)), such that this information is equally accessible to Plaintiffs as it is to Defendants. For that reason, Defendants do not intend at this time to re-review these files to identify that information.

r. Operating procedures associated with a product development cycle;

ETH.MESH.03743022-ETH.MESH.03743040
ETH.MESH.06378531-ETH.MESH.06378564

s. The Devices' quality manuals;

ETH.MESH.03739845-ETH.MESH.03739883
ETH.MESH.03740357-ETH.MESH.03740407

t. The Devices' quality plans;

ETH.MESH.01589786-ETH.MESH.01589786
ETH.MESH.00302537-ETH.MESH.00302542
ETH.MESH.01592172-ETH.MESH.01592176
ETH.MESH.00223172-ETH.MESH.00223173
ETH.MESH.01593040-ETH.MESH.01593045
ETH.MESH.00754756-ETH.MESH.00754756
ETH.MESH.01418538-ETH.MESH.01418538
ETH.MESH.01592791-ETH.MESH.01592796

u. Management responsibilities under a quality system;

Defendants will continue to search to determine whether any documents responsive to this Request have been produced or should be produced and invite Plaintiffs to meet and confer on this issue.

v. Mesh product design review, design verification, process qualification and design transfer;

ETH.MESH.00309254-ETH.MESH.00309350
ETH.MESH.01309985-ETH.MESH.01309988
ETH.MESH.00748032-ETH.MESH.00748033
ETH.MESH.00858217-ETH.MESH.00858224
ETH.MESH.00858264-ETH.MESH.00858264
ETH.MESH.00858266-ETH.MESH.00858268
ETH.MESH.00858270-ETH.MESH.00858270
ETH.MESH.00858272-ETH.MESH.00858278
ETH.MESH.00867295-ETH.MESH.00867295
ETH.MESH.01409160-ETH.MESH.01409161
ETH.MESH.01409491-ETH.MESH.01409504

ETH.MESH.01318365-ETH.MESH.00222945
ETH.MESH.00222649-ETH.MESH.00222650
ETH.MESH.00223198-ETH.MESH.00223267
ETH.MESH.00222977-ETH.MESH.00223040
ETH.MESH.00223648-ETH.MESH.00223648
ETH.MESH.00223800-ETH.MESH.00223828
ETH.MESH.00755002-ETH.MESH.00755005
ETH.MESH.01419928-ETH.MESH.01419931
ETH.MESH.01419934-ETH.MESH.01419963
ETH.MESH.00223592-ETH.MESH.00223617
ETH.MESH.00223625-ETH.MESH.00223632
ETH.MESH.00223793-ETH.MESH.00754538
ETH.MESH.00754595-ETH.MESH.01414728
ETH.MESH.01414762-ETH.MESH.01414762
ETH.MESH.01417706-ETH.MESH.01417982
ETH.MESH.01589884-ETH.MESH.01589986
ETH.MESH.01594413-ETH.MESH.01594444
ETH.MESH.02312661-ETH.MESH.02312663

w. Mesh product device design requirements matrix;

ETH.MESH.01316771-ETH.MESH.01316776
ETH.MESH.00748022-ETH.MESH.00748031
ETH.MESH.01409306-ETH.MESH.01409348
ETH.MESH.00748011-ETH.MESH.00748014
ETH.MESH.01419895-ETH.MESH.01419914
ETH.MESH.01414512-ETH.MESH.01414552
ETH.MESH.01414644-ETH.MESH.01414710
ETH.MESH.01414553-ETH.MESH.01414643

x. Mesh product qualitative and quantitative characteristics worksheets, including but not limited to hazard worksheet raking (sic) tables;

ETH.MESH.01310064-ETH.MESH.01310064
ETH.MESH.00752933-ETH.MESH.00752934
ETH.MESH.00222371-ETH.MESH.00222380
ETH.MESH.00222381-ETH.MESH.00222388
ETH.MESH.01419739-ETH.MESH.01419739
ETH.MESH.01418543-ETH.MESH.01418543
ETH.MESH.01593319-ETH.MESH.01593320

y. Mesh product validation test reports; and

ETH.MESH.00748214-ETH.MESH.00748262
ETH.MESH.00307449-ETH.MESH.00307451
ETH.MESH.00307471-ETH.MESH.00307484

ETH.MESH.00307492-ETH.MESH.00307526
ETH.MESH.01409023-ETH.MESH.01409058
ETH.MESH.01592121-ETH.MESH.01592171
ETH.MESH.00222788-ETH.MESH.00222880
ETH.MESH.00754928-ETH.MESH.00754969
ETH.MESH.01419932-ETH.MESH.01419933
ETH.MESH.00754785-ETH.MESH.00754857
ETH.MESH.01418738-ETH.MESH.01419737
ETH.MESH.01591886-ETH.MESH.01591913
ETH.MESH.01592406-ETH.MESH.01592433
ETH.MESH.01592438-ETH.MESH.01592488
ETH.MESH.01592696-ETH.MESH.01592756
ETH.MESH.01592760-ETH.MESH.01592781
ETH.MESH.01592800-ETH.MESH.01592867
ETH.MESH.01592899-ETH.MESH.01593008
ETH.MESH.01593301-ETH.MESH.01593314
ETH.MESH.01593358-ETH.MESH.01593380

z. Mesh product biocompatibility testing records.

ETH.MESH.01316900-ETH.MESH.01316899
ETH.MESH.01309984-ETH.MESH.01309984
ETH.MESH.01409564-ETH.MESH.01409602
ETH.MESH.01409820-ETH.MESH.01409849
ETH.MESH.00222475-ETH.MESH.00222577
ETH.MESH.01419742-ETH.MESH.01419745
ETH.MESH.00348897-ETH.MESH.00348899
ETH.MESH.00754441-ETH.MESH.00754442
ETH.MESH.01320389-ETH.MESH.01320394
ETH.MESH.01413955-ETH.MESH.01414252

Document Request No. 6: All documents concerning your protocol or standard operating procedures (SOP) not listed in number 3 above for:

a. Your design and development department;

b. Your risk management department;

c. Your quality assurance department; and

d. Testing and Validation of the Devices.

Responses and Objections to Document Request No. 6: Defendants object that this request is overbroad and unduly burdensome. The design and development of the Devices were long term projects, taking a total of more than a dozen years from TVT to TVT Exact and Abbrevo. Thus, the Standard Operating Procedures associated with each device were revised multiple times over the course of this time period. Defendants object that this request is dramatically overbroad since there will be numerous standard operating procedures applicable to the design of the Devices that have no bearing on this litigation.

Subject to and without waiving any objections, Defendants will produce documents that may be responsive to this request, to the extent such documents are reasonably available to Defendants. Below are the Bates ranges of previously produced documents that Defendants believe are responsive to each subpart of this request:

a. Your design and development department;

ETH.MESH.03741952-ETH.MESH.03741953
ETH.MESH.03742863-ETH.MESH.03742863
ETH.MESH.05405810-ETH.MESH.05405832

b. Your risk management department;

ETH.MESH.03740512-ETH.MESH.03740522
ETH.MESH.03742021-ETH.MESH.03742031
ETH.MESH.03742996-ETH.MESH.03743005

c. Your quality assurance department; and

ETH.MESH.03739207-ETH.MESH.03739211
ETH.MESH.03739350-ETH.MESH.03739355
ETH.MESH.03743412-ETH.MESH.03743435
ETH.MESH.03743537-ETH.MESH.03743551
ETH.MESH.03743627-ETH.MESH.03743635
ETH.MESH.03743636-ETH.MESH.03743644
ETH.MESH.03743654-ETH.MESH.03743663
ETH.MESH.03743688-ETH.MESH.03743694
ETH.MESH.03743695-ETH.MESH.03743698

ETH.MESH.03743699-ETH.MESH.03743704
ETH.MESH.03743708-ETH.MESH.03743723
ETH.MESH.03744330-ETH.MESH.03744353
ETH.MESH.03744358-ETH.MESH.03744358
ETH.MESH.03744359-ETH.MESH.03744359
ETH.MESH.03744360-ETH.MESH.03744360
ETH.MESH.03744361-ETH.MESH.03744361
ETH.MESH.03744362-ETH.MESH.03744362
ETH.MESH.03744363-ETH.MESH.03744363
ETH.MESH.03744364-ETH.MESH.03744364
ETH.MESH.03744365-ETH.MESH.03744365
ETH.MESH.03744366-ETH.MESH.03744366
ETH.MESH.03744367-ETH.MESH.03744367
ETH.MESH.03744368-ETH.MESH.03744368
ETH.MESH.03744369-ETH.MESH.03744383
ETH.MESH.03744385-ETH.MESH.03744389
ETH.MESH.03744464-ETH.MESH.03744465
ETH.MESH.03744466-ETH.MESH.03744466
ETH.MESH.03744467-ETH.MESH.03744467

d. Testing and Validation of the Devices.

Defendants will continue to search to determine whether any documents responsive to this Request have been produced or should be produced and invite Plaintiffs to meet and confer on this issue.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ David B. Thomas
David B. Thomas (W. Va. Bar No. 3731)
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/s/ Christy D. Jones
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION **THIS DOCUMENT RELATES TO ALL CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on April 10, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

*_/s/ David B. Thomas_*
David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

AMENDED NOTICE TO TAKE ORAL DEPOSITION
OF DEFENDANT THROUGH DESIGNATED WITNESS REGARDING TVT-O

TO: Defendants ETHICON, INC., Johnson & Johnson, Inc., (hereinafter "Defendants") and their Attorneys of Record

Please take notice that pursuant Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of Defendants' corporate designee regarding TVT-O to begin on May 15, 2013, at 9:00 a.m., at the offices of Riker Danzig at One Speedwell Avenue in Morristown, New Jersey. The witness shall be prepared to testify concerning the subject matters identified in Exhibit "A", attached hereto. The witness shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day to day until the examination is completed.

DEFINITIONS

All definitions and rules of instructions set forth in Fed. R. Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device

industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. "Concerning" means referring to, describing, evidencing, or constituting. See LR. Civ. P. 26.2(c)(7).

2. "Defendants", "Ethicon, Inc.", "Johnson & Johnson Inc.", "you" or "your" refers to, without limitation, Ethicon, Inc., and Johnson & Johnson Inc., and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. "Document" is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR. Civ. P. 26.2(c)(2); *see also* Fed. R. Civ. P. 34(a).

4. "TVT-O" means the TVT-Obturator device cleared by the FDA on or about December 08, 2003 which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).

5. "Relevant Time Period" means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold TVT-O to the present.

PLAINTIFFS' CO-LEAD COUNSEL

By: _____/s/Thomas P. Cartmell________________

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Plaintiffs' Co-Lead Counsel

EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge of and shall be able to testify concerning the following subject matters related to "TVT-O" defined in Paragraph 4 of Notice of Deposition:

I. DESIGN AND DEVELOPMENT OF MESH PRODCUTS

a. The Standard Operating Procedures (SOP) associated with design and development of TVT-O;

b. The complete design history file for TVT-O, including each component part of the file, the custodian responsible for the file and the maintenance of the file;

c. Members and procedures of the Product Development Team for TVT-O;

d. The Operating Procedures associated with Product Development Cycle;

e. The Design Output file, including the specifications of the TVT-O;

f. The user needs and design requirements for the TVT-O;

g. The Cadaver Lab evaluations for the TVT-O;

h. The specifics of all testing related to the TVT-O during the design and development stages, including but not limited to bench testing, porosity testing, particle loss, fraying, degradation, and leaching;

i. All project names of the TVT-O;

j. Design verification of the TVT-O;

k. Design validation of the TVT-O;

l. The Design Review, Process Qualification (PQ) and Design Transfer for the TVT-O;

m. The Product Device Design Safety Assessment (DDSA) and the policies and procedures related to these analyses;

n. Product Device Design Failure Modes Effects Analysis (dFMEA), Process Failure Modes Effects Analysis (pFMEA) and Application Failure Modes Effects Analysis (aFMEA);

o. The Product Device Design Requirements Matrix;

p. The Product Device Qualitative and Quantitative Characteristics Worksheets, including but not limited to Hazard Worksheet and ranking tables;

q. The Clinical Validation Test Reports;Procedures for preparing and keeping Minutes and Agendas for Design Review Meetings;

r. As it relates to design control and validation, any and all discussions or documents related to whether or not to design, develop, coordinate, create, participate in and/or fund any clinical registries regarding your TVT-O;

s. Any patents related to the TVT-O and its predecessor mesh products;

t. The identity of and financial compensation paid to any consultants retained during the design and development of the TVT-O;

u. The monitoring, investigation and evaluation of post-marketing adverse event reports for your TVT-O for design issues;

v. The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding your TVT-O for design issues;

w. As it relates to design control and validation, the investigation, evaluation and determination as to whether there is an association between the design of TVT-O and any adverse event experienced by patients who were provided your TVT-O;

x. The investigation, evaluation and determination as to whether there is a causal connection between the design of your TVT-O and any adverse event or injuries;

y. The substantive design and approval of package inserts, IFUs, and other labeling for your TVT-O (both U.S. and foreign), including the specific dates of use for each such items and any design changes thereto;

ii. The maintenance of Ethicon Inc.'s finances, budgets and expenditures with regard to design and development related to its TVT-O from the date first started developing its TVT-O until the present;

jj. The interaction and communication internally or with any outside consultants regarding the design specifications, including conformance to specifications of your TVT-O, from the date Ethicon, Inc. first started developing TVT-O until the present;

kk. As they relate to design control and validation, the manufacturing processes, including but not limited to heating/extrusion/annealing/cooling/gamma radiation/sterilization;

z. The identity of the individuals involved the defendants' original decision to design, develop and manufacture the TVT-O;

aa. All medical assessments of the TVT-O as it relates to the design control and validation process;

bb. The specifics of all clinical, preclinical, and medical testing related to the TVT-O during the design and development stages;

cc. Animal Testing Records for Biocompatibility as part of the design of the product;

dd. The evaluation of data and results of any pre-clinical studies, clinical trials and testing regarding your TVT-O;

ee. The development and coordination of any pre-clinical studies, clinical trials and design testing regarding your TVT-O;

EXHIBIT "B"

DOCUMENT REQUESTS

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.

2. Two exemplar products for all products listed in "TVT-O" definition above.

3. Prototype meshes and samples/pathology/histopathology slides of all pathology testing on TVT-O.

4. All documents concerning corporate, departmental, and employee organizational charts for your design and development department, product development or product cycle teams.

5. The following documents for the design and development of TVT-O, including but not limited to:

   a. The Clinical Expert reports;

   b. Each version of the Device Design Safety Assessment (DDSA's); Each version of the Design Failure Modes Effects Analysis (dFMEAs), Process Failure Modes Effects Analysis (pFMEAs), Application Failure Modes Effects Analysis (aFMEA);

   c. Operating Procedures for Failure Modes and Effects Analysis;

   d. Operating Procedure for Device Design Safety Assessment;

   e. Design history files;

   f. Design and specifications of equipment used in the production of TVT-O;

   g. Design and specifications of packaging used in the production of TVT-O;

   h. Specifications regarding sanitization and sterilization of TVT-O, plant facilities and plant equipment;

   i. Mesh Specifications;

   j. Franchise procedure for medical device risk management plan;

   k. Company procedure for medical device risk management plan;

   l. Work Instruction for device risk management;

   m. The Franchise procedure for the control and disposition of nonconforming product;

n. All company policies and procedures that apply to or relate to the Design History File;

o. The Franchise Procedure for Corrective and Preventative Action (CAPA) as well as any other company policies and procedures related to CAPAs;

p. Risk management plans and reports for TVT-O;

q. Members of product development team(s);

r. Operating procedures associated with a product development cycle;

s. TVT-O quality manual;

t. TVT-O quality plan;

u. Management responsibilities under a quality system;

v. Mesh product design review, design verification, process qualification and design transfer;

w. Mesh product device design requirements matrix;

x. Mesh product qualitative and quantitative characteristics worksheets, including but not omitted to hazard worksheet raking tables;

y. Mesh product validation test reports; and

z. Mesh product biocompatibility testing records;

6. All documents concerning your protocol or standard operating procedures (SOP) not listed in number 3 above for:

a. Your design and development department;

b. Your risk management department;

c. Your quality assurance department; and

d. Testing and Validation of TVT-O.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	CIVIL ACTION NO. 2:12-md-02327 MDL No. 2327
	Judge Joseph R. Goodwin
This Document Applies To All Actions	

To: Christy D. Jones, Esq.
Butler, Snow, O'Mara Stevens & Cannada, PLLC
1020 Highland Colony Parkway, Suite 1400
Ridgeland, MS 39157
601-948-5711

PLAINTIFFS' CERTIFICATE OF SERVICE OF AMENDED NOTICE TO TAKE ORAL DEPOSITION OF DEFENDANT THROUGH DESIGNATED WITNESS REGARDING TVT-O

I hereby certify that on April 2. 2013, I served Plaintiff's Amended Notice to Take Oral Deposition of Defendant through Designated Witness regarding TVT-O via email and the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/Thomas P. Cartmell

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Rbaggett@awkolaw.com
Plaintiffs' Co-Lead Counsel

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

**AMENDED NOTICE TO TAKE ORAL DEPOSITION
OF DEFENDANT THROUGH DESIGNATED WITNESS REGARDING TVT-A**

TO: Defendants ETHICON, INC., Johnson & Johnson, Inc., (hereinafter "Defendants") and their Attorneys of Record

Please take notice that pursuant Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of Defendants' corporate designee regarding TVT-A to begin on May 15, 2013, at 9:00 a.m., at the offices of Riker Danzig at One Speedwell Avenue in Morristown, New Jersey. The witness shall be prepared to testify concerning the subject matters identified in Exhibit "A", attached hereto. The witness shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day to day until the examination is completed.

DEFINITIONS

All definitions and rules of instructions set forth in Fed. R. Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device

industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. "Concerning" means referring to, describing, evidencing, or constituting. See LR. Civ. P. 26.2(c)(7).

2. "Defendants", "Ethicon, Inc.", "Johnson & Johnson Inc.", "you" or "your" refers to, without limitation, Ethicon, Inc., and Johnson & Johnson Inc., and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. "Document" is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR. Civ. P. 26.2(c)(2); *see also* Fed. R. Civ. P. 34(a).

4. "TVT-A" means the TVT-Abbrevo Tension Free Vaginal Tape cleared by the FDA on or about July 1, 2010 which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).

5. "Relevant Time Period" means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold TVT-A to the present.

PLAINTIFFS' CO-LEAD COUNSEL

By: /s/Thomas P. Cartmell
THOMAS P. CARTMELL
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Rbaggett@awkolaw.com
Plaintiffs' Co-Lead Counsel

EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge of and shall be able to testify concerning the following subject matters related to "TVT-A" defined in Paragraph 4 of Notice of Deposition:

I. DESIGN AND DEVELOPMENT OF MESH PRODCUTS

a. The Standard Operating Procedures (SOP) associated with design and development of TVT-A;

b. The complete design history file for TVT-A, including each component part of the file, the custodian responsible for the file and the maintenance of the file;

c. Members and procedures of the Product Development Team for TVT-A;

d. The Operating Procedures associated with Product Development Cycle;

e. The Design Output file, including the specifications of the TVT-A;

f. The user needs and design requirements for the TVT-A;

g. The Cadaver Lab evaluations for the TVT-A;

h. The specifics of all testing related to the TVT-A during the design and development stages, including but not limited to bench testing, porosity testing, particle loss, fraying, degradation, and leaching;

i. All project names of the TVT-A;

j. Design verification of the TVT-A;

k. Design validation of the TVT-A;

l. The Design Review, Process Qualification (PQ) and Design Transfer for the TVT-A;

m. The Product Device Design Safety Assessment (DDSA) and the policies and procedures related to these analyses;

n. Product Device Design Failure Modes Effects Analysis (dFMEA), Process Failure Modes Effects Analysis (pFMEA) and Application Failure Modes Effects Analysis (aFMEA);

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o. The Product Device Design Requirements Matrix;

p. The Product Device Qualitative and Quantitative Characteristics Worksheets, including but not limited to Hazard Worksheet and ranking tables;

q. The Clinical Validation Test Reports;Procedures for preparing and keeping Minutes and Agendas for Design Review Meetings;

r. As it relates to design control and validation, any and all discussions or documents related to whether or not to design, develop, coordinate, create, participate in and/or fund any clinical registries regarding your TVT-A;

s. Any patents related to the TVT-A and its predecessor mesh products;

t. The identity of and financial compensation paid to any consultants retained during the design and development of the TVT-A;

u. The monitoring, investigation and evaluation of post-marketing adverse event reports for your TVT-A for design issues;

v. The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding your TVT-A for design issues;

w. As it relates to design control and validation, the investigation, evaluation and determination as to whether there is an association between the design of TVT-A and any adverse event experienced by patients who were provided your TVT-A;

x. The investigation, evaluation and determination as to whether there is a causal connection between the design of your TVT-A and any adverse event or injuries;

y. The substantive design and approval of package inserts, IFUs, and other labeling for your TVT-A (both U.S. and foreign), including the specific dates of use for each such items and any design changes thereto;

ii. The maintenance of Ethicon Inc.'s finances, budgets and expenditures with regard to design and development related to its TVT-A from the date first started developing its TVT-A until the present;

jj. The interaction and communication internally or with any outside consultants regarding the design specifications, including conformance to specifications of your TVT-A, from the date Ethicon, Inc. first started developing TVT-A until the present;

kk. As they relate to design control and validation, the manufacturing processes, including but not limited to heating/extrusion/annealing/cooling/gamma radiation/sterilization;

z. The identity of the individuals involved the defendants' original decision to design, develop and manufacture the TVT-A;

aa. All medical assessments of the TVT-A as it relates to the design control and validation process;

bb. The specifics of all clinical, preclinical, and medical testing related to the TVT-A during the design and development stages;

cc. Animal Testing Records for Biocompatibility as part of the design of the product;

dd. The evaluation of data and results of any pre-clinical studies, clinical trials and testing regarding your TVT-A;

ee. The development and coordination of any pre-clinical studies, clinical trials and design testing regarding your TVT-A;

EXHIBIT "B"

DOCUMENT REQUESTS

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.

2. Two exemplar products for all products listed in "TVT-A" definition above.

3. Prototype meshes and tissue samples/pathology/histopathology slides of all pathology testing on TVT-A.

4. All documents concerning corporate, departmental, and employee organizational charts for your design and development department, product development or product cycle teams.

5. The following documents for the design and development of TVT-A, including but not limited to:

   a. The Clinical Expert reports;

   b. Each version of the Device Design Safety Assessment (DDSA's); Each version of the Design Failure Modes Effects Analysis (dFMEAs), Process Failure Modes Effects Analysis (pFMEAs), Application Failure Modes Effects Analysis (aFMEA);

   c. Operating Procedures for Failure Modes and Effects Analysis;

   d. Operating Procedure for Device Design Safety Assessment;

   e. Design history files;

   f. Design and specifications of equipment used in the production of TVT-A;

   g. Design and specifications of packaging used in the production of TVT-A;

   h. Specifications regarding sanitization and sterilization of TVT-A, plant facilities and plant equipment;

   i. Mesh Specifications;

   j. Franchise procedure for medical device risk management plan;

   k. Company procedure for medical device risk management plan;

   l. Work Instruction for device risk management;

   m. The Franchise procedure for the control and disposition of nonconforming product;

n. All company policies and procedures that apply to or relate to the Design History File;

o. The Franchise Procedure for Corrective and Preventative Action (CAPA) as well as any other company policies and procedures related to CAPAs;

p. Risk management plans and reports for TVT-A;

q. Members of product development team(s);

r. Operating procedures associated with a product development cycle;

s. TVT-A quality manual;

t. TVT-A quality plan;

u. Management responsibilities under a quality system;

v. Mesh product design review, design verification, process qualification and design transfer;

w. Mesh product device design requirements matrix;

x. Mesh product qualitative and quantitative characteristics worksheets, including but not omitted to hazard worksheet raking tables;

y. Mesh product validation test reports; and

z. Mesh product biocompatibility testing records;

6. All documents concerning your protocol or standard operating procedures (SOP) not listed in number 3 above for:

a. Your design and development department;

b. Your risk management department;

c. Your quality assurance department; and

d. Testing and Validation of TVT-A.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	CIVIL ACTION NO. 2:12-md-02327 MDL No. 2327
	:	Judge Joseph R. Goodwin
This Document Applies To All Actions	:	

To: Christy D. Jones, Esq.
Butler, Snow, O'Mara Stevens & Cannada, PLLC
1020 Highland Colony Parkway, Suite 1400
Ridgeland, MS 39157
601-948-5711

PLAINTIFFS' CERTIFICATE OF SERVICE OF AMENDED NOTICE TO TAKE ORAL DEPOSITION OF DEFENDANT THROUGH DESIGNATED WITNESS REGARDING TVT-A

I hereby certify that on April 2. 2013, I served Plaintiff's Amended Notice to Take Oral Deposition of Defendant through Designated Witness regarding TVT-A via email and the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/Thomas P. Cartmell

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Plaintiffs' Co-Lead Counsel

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

AMENDED NOTICE TO TAKE ORAL DEPOSITION
OF DEFENDANT THROUGH DESIGNATED WITNESS REGARDING TVT-CLASSIC

TO: Defendants ETHICON, INC., Johnson & Johnson, Inc., (hereinafter "Defendants") and their Attorneys of Record

Please take notice that pursuant Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of Defendants' corporate designee regarding TVT-Classic to begin on May 15, 2013, at 9:00 a.m., at the offices of Riker Danzig at One Speedwell Avenue in Morristown, New Jersey. The witness shall be prepared to testify concerning the subject matters identified in Exhibit "A", attached hereto. The witness shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day to day until the examination is completed.

DEFINITIONS

All definitions and rules of instructions set forth in Fed. R. Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device

industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. "Concerning" means referring to, describing, evidencing, or constituting. See LR. Civ. P. 26.2(c)(7).

2. "Defendants", "Ethicon, Inc.", "Johnson & Johnson Inc.", "you" or "your" refers to, without limitation, Ethicon, Inc., and Johnson & Johnson Inc., and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. "Document" is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR. Civ. P. 26.2(c)(2); *see also* Fed. R. Civ. P. 34(a).

4. "TVT" means the TVT "classic" Tension Free Vaginal Tape System cleared by the FDA on or about January 01, 1998, which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI). The term "TVT" also includes any kits or tools designed to be sold with the TVT including, but not limited to the TVT-AA and TVT-D.

5. "Relevant Time Period" means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold TVT to the present.

PLAINTIFFS' CO-LEAD COUNSEL

By: /s/Thomas P. Cartmell
THOMAS P. CARTMELL
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Rbaggett@awkolaw.com
Plaintiffs' Co-Lead Counsel

EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge of and shall be able to testify concerning the following subject matters related to "TVT" defined in Paragraph 4 of Notice of Deposition:

I. DESIGN AND DEVELOPMENT OF MESH PRODCUTS

a. The Standard Operating Procedures (SOP) associated with design and development of TVT;

b. The complete design history file for TVT, including each component part of the file, the custodian responsible for the file and the maintenance of the file;

c. Members and procedures of the Product Development Team for TVT;

d. The Operating Procedures associated with Product Development Cycle;

e. The Design Output file, including the specifications of the TVT;

f. The user needs and design requirements for the TVT;

g. The Cadaver Lab evaluations for the TVT;

h. The specifics of all testing related to the TVT during the design and development stages, including but not limited to bench testing, porosity testing, particle loss, fraying, degradation, and leaching;

i. All project names of the TVT;

j. Design verification of the TVT;

k. Design validation of the TVT;

l. The Design Review, Process Qualification (PQ) and Design Transfer for the TVT;

m. The Product Device Design Safety Assessment (DDSA) and the policies and procedures related to these analyses;

n. Product Device Design Failure Modes Effects Analysis (dFMEA), Process Failure Modes Effects Analysis (pFMEA) and Application Failure Modes Effects Analysis (aFMEA);

o. The Product Device Design Requirements Matrix;

p. The Product Device Qualitative and Quantitative Characteristics Worksheets, including but not limited to Hazard Worksheet and ranking tables;

q. The Clinical Validation Test Reports;Procedures for preparing and keeping Minutes and Agendas for Design Review Meetings;

r. As it relates to design control and validation, any and all discussions or documents related to whether or not to design, develop, coordinate, create, participate in and/or fund any clinical registries regarding your TVT;

s. Any patents related to the TVT and its predecessor mesh products;

t. The identity of and financial compensation paid to any consultants retained during the design and development of the TVT;

u. The monitoring, investigation and evaluation of post-marketing adverse event reports for your TVT for design issues;

v. The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding your TVT for design issues;

w. As it relates to design control and validation, the investigation, evaluation and determination as to whether there is an association between the design of TVT and any adverse event experienced by patients who were provided your TVT;

x. The investigation, evaluation and determination as to whether there is a causal connection between the design of your TVT and any adverse event or injuries;

y. The substantive design and approval of package inserts, IFUs, and other labeling for your TVT (both U.S. and foreign), including the specific dates of use for each such items and any design changes thereto;

ii. The maintenance of Ethicon Inc.'s finances, budgets and expenditures with regard to design and development related to its TVT from the date first started developing its TVT until the present;

jj. The interaction and communication internally or with any outside consultants regarding the design specifications, including conformance to specifications of your TVT, from the date Ethicon, Inc. first started developing TVT until the present;

kk. As they relate to design control and validation, the manufacturing processes, including but not limited to heating/extrusion/annealing/cooling/gamma radiation/sterilization;

z. The identity of the individuals involved the defendants' original decision to design, develop and manufacture the TVT;

aa. All medical assessments of the TVT as it relates to the design control and validation process;

bb. The specifics of all clinical, preclinical, and medical testing related to the TVT during the design and development stages;

cc. Animal Testing Records for Biocompatibility as part of the design of the product;

dd. The evaluation of data and results of any pre-clinical studies, clinical trials and testing regarding your TVT;

ee. The development and coordination of any pre-clinical studies, clinical trials and design testing regarding your TVT;

EXHIBIT "B"

DOCUMENT REQUESTS

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.

2. Two exemplar products for all products listed in "TVT" definition above.

3. Prototype meshes and tissue samples/pathology/histopathology slides of all pathology testing on TVT.

4. All documents concerning corporate, departmental, and employee organizational charts for your design and development department, product development or product cycle teams.

5. The following documents for the design and development of TVT, including but not limited to:

   a. The Clinical Expert reports;

   b. Each version of the Device Design Safety Assessment (DDSA's); Each version of the Design Failure Modes Effects Analysis (dFMEAs), Process Failure Modes Effects Analysis (pFMEAs), Application Failure Modes Effects Analysis (aFMEA);

   c. Operating Procedures for Failure Modes and Effects Analysis;

   d. Operating Procedure for Device Design Safety Assessment;

   e. Design history files;

   f. Design and specifications of equipment used in the production of TVT;

   g. Design and specifications of packaging used in the production of TVT;

   h. Specifications regarding sanitization and sterilization of TVT, plant facilities and plant equipment;

   i. Mesh Specifications;

   j. Franchise procedure for medical device risk management plan;

   k. Company procedure for medical device risk management plan;

   l. Work Instruction for device risk management;

   m. The Franchise procedure for the control and disposition of nonconforming product;

n. All company policies and procedures that apply to or relate to the Design History File;

o. The Franchise Procedure for Corrective and Preventative Action (CAPA) as well as any other company policies and procedures related to CAPAs;

p. Risk management plans and reports for TVT;

q. Members of product development team(s);

r. Operating procedures associated with a product development cycle;

s. TVT quality manual;

t. TVT quality plan;

u. Management responsibilities under a quality system;

v. Mesh product design review, design verification, process qualification and design transfer;

w. Mesh product device design requirements matrix;

x. Mesh product qualitative and quantitative characteristics worksheets, including but not omitted to hazard worksheet raking tables;

y. Mesh product validation test reports; and

z. Mesh product biocompatibility testing records;

6. All documents concerning your protocol or standard operating procedures (SOP) not listed in number 3 above for:

a. Your design and development department;

b. Your risk management department;

c. Your quality assurance department; and

d. Testing and Validation of TVT.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	CIVIL ACTION NO. 2:12-md-02327 MDL No. 2327
	:	Judge Joseph R. Goodwin
This Document Applies To All Actions	:	

To: Christy D. Jones, Esq.
Butler, Snow, O'Mara Stevens & Cannada, PLLC
1020 Highland Colony Parkway, Suite 1400
Ridgeland, MS 39157
601-948-5711

PLAINTIFFS' CERTIFICATE OF SERVICE OF AMENDED NOTICE TO TAKE ORAL DEPOSITION OF DEFENDANT THROUGH DESIGNATED WITNESS REGARDING TVT-CLASSIC

I hereby certify that on April 2. 2013, I served Plaintiff's Amended Notice to Take Oral Deposition of Defendant through Designated Witness regarding TVT-Classic via email and the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/Thomas P. Cartmell

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Plaintiffs' Co-Lead Counsel

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

AMENDED NOTICE TO TAKE ORAL DEPOSITION
OF DEFENDANT THROUGH DESIGNATED WITNESS REGARDING TVT-S

TO: Defendants ETHICON, INC., Johnson & Johnson, Inc., (hereinafter "Defendants") and their Attorneys of Record

Please take notice that pursuant Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of Defendants' corporate designee regarding TVT-S to begin on May 15, 2013, at 9:00 a.m., at the offices of Riker Danzig at One Speedwell Avenue in Morristown, New Jersey. The witness shall be prepared to testify concerning the subject matters identified in Exhibit "A", attached hereto. The witness shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day to day until the examination is completed.

DEFINITIONS

All definitions and rules of instructions set forth in Fed. R. Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device

industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. "Concerning" means referring to, describing, evidencing, or constituting. See LR. Civ. P. 26.2(c)(7).

2. "Defendants", "Ethicon, Inc.", "Johnson & Johnson Inc.", "you" or "your" refers to, without limitation, Ethicon, Inc., and Johnson & Johnson Inc., and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. "Document" is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR. Civ. P. 26.2(c)(2); *see also* Fed. R. Civ. P. 34(a).

4. "TVT-S" means the TVT-Secur device cleared by the FDA on or about November 28, 2005 which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).

5. "Relevant Time Period" means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold TVT-S to the present.

PLAINTIFFS' CO-LEAD COUNSEL

By: ____/s/Thomas P. Cartmell____

THOMAS P. CARTMELL
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Rbaggett@awkolaw.com
Plaintiffs' Co-Lead Counsel

EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge of and shall be able to testify concerning the following subject matters related to "TVT-S" defined in Paragraph 4 of Notice of Deposition:

I. DESIGN AND DEVELOPMENT OF MESH PRODCUTS

a. The Standard Operating Procedures (SOP) associated with design and development of TVT-S;

b. The complete design history file for TVT-S, including each component part of the file, the custodian responsible for the file and the maintenance of the file;

c. Members and procedures of the Product Development Team for TVT-S;

d. The Operating Procedures associated with Product Development Cycle;

e. The Design Output file, including the specifications of the TVT-S;

f. The user needs and design requirements for the TVT-S;

g. The Cadaver Lab evaluations for the TVT-S;

h. The specifics of all testing related to the TVT-S during the design and development stages, including but not limited to bench testing, porosity testing, particle loss, fraying, degradation, and leaching;

i. All project names of the TVT-S;

j. Design verification of the TVT-S;

k. Design validation of the TVT-S;

l. The Design Review, Process Qualification (PQ) and Design Transfer for the TVT-S;

m. The Product Device Design Safety Assessment (DDSA) and the policies and procedures related to these analyses;

n. Product Device Design Failure Modes Effects Analysis (dFMEA), Process Failure Modes Effects Analysis (pFMEA) and Application Failure Modes Effects Analysis (aFMEA);

o. The Product Device Design Requirements Matrix;

p. The Product Device Qualitative and Quantitative Characteristics Worksheets, including but not limited to Hazard Worksheet and ranking tables;

q. The Clinical Validation Test Reports;Procedures for preparing and keeping Minutes and Agendas for Design Review Meetings;

r. As it relates to design control and validation, any and all discussions or documents related to whether or not to design, develop, coordinate, create, participate in and/or fund any clinical registries regarding your TVT-S;

s. Any patents related to the TVT-S and its predecessor mesh products.

t. The identity of and financial compensation paid to any consultants retained during the design and development of the TVT-S;

u. The monitoring, investigation and evaluation of post-marketing adverse event reports for your TVT-S for design issues;

v. The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding your TVT-S for design issues;

w. As it relates to design control and validation, the investigation, evaluation and determination as to whether there is an association between the design of TVT-S and any adverse event experienced by patients who were provided your TVT-S;

x. The investigation, evaluation and determination as to whether there is a causal connection between the design of your TVT-S and any adverse event or injuries;

y. The substantive design and approval of package inserts, IFUs, and other labeling for your TVT-S (both U.S. and foreign), including the specific dates of use for each such items and any design changes thereto;

ii. The maintenance of Ethicon Inc.'s finances, budgets and expenditures with regard to design and development related to its TVT-S from the date first started developing its TVT-S until the present;

jj. The interaction and communication internally or with any outside consultants regarding the design specifications, including conformance to specifications of your TVT-S, from the date Ethicon, Inc. first started developing TVT-S until the present;

kk. As they relate to design control and validation, the manufacturing processes, including but not limited to heating/extrusion/annealing/cooling/gamma radiation/sterilization;

z. The identity of the individuals involved the defendants' original decision to design, develop and manufacture the TVT-S;

aa. All medical assessments of the TVT-S as it relates to the design control and validation process;

bb. The specifics of all clinical, preclinical, and medical testing related to the TVT-S during the design and development stages;

cc. Animal Testing Records for Biocompatibility as part of the design of the product;

dd. The evaluation of data and results of any pre-clinical studies, clinical trials and testing regarding your TVT-S;

ee. The development and coordination of any pre-clinical studies, clinical trials and design testing regarding your TVT-S;

EXHIBIT "B"

DOCUMENT REQUESTS

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.

2. Two exemplar products for all products listed in "TVT-S" definition above.

3. Prototype meshes and tissue samples/pathology/histopathology slides of all pathology testing on TVT-S.

4. All documents concerning corporate, departmental, and employee organizational charts for your design and development department, product development or product cycle teams.

5. The following documents for the design and development of TVT-S, including but not limited to:

   a. The Clinical Expert reports;

   b. Each version of the Device Design Safety Assessment (DDSA's); Each version of the Design Failure Modes Effects Analysis (dFMEAs), Process Failure Modes Effects Analysis (pFMEAs), Application Failure Modes Effects Analysis (aFMEA);

   c. Operating Procedures for Failure Modes and Effects Analysis;

   d. Operating Procedure for Device Design Safety Assessment;

   e. Design history files;

   f. Design and specifications of equipment used in the production of TVT-S;

   g. Design and specifications of packaging used in the production of TVT-S;

   h. Specifications regarding sanitization and sterilization of TVT-S, plant facilities and plant equipment;

   i. Mesh Specifications;

   j. Franchise procedure for medical device risk management plan;

   k. Company procedure for medical device risk management plan;

   l. Work Instruction for device risk management;

   m. The Franchise procedure for the control and disposition of nonconforming product;

n. All company policies and procedures that apply to or relate to the Design History File;

o. The Franchise Procedure for Corrective and Preventative Action (CAPA) as well as any other company policies and procedures related to CAPAs;

p. Risk management plans and reports for TVT-S;

q. Members of product development team(s);

r. Operating procedures associated with a product development cycle;

s. TVT-S quality manual;

t. TVT-S quality plan;

u. Management responsibilities under a quality system;

v. Mesh product design review, design verification, process qualification and design transfer;

w. Mesh product device design requirements matrix;

x. Mesh product qualitative and quantitative characteristics worksheets, including but not omitted to hazard worksheet raking tables;

y. Mesh product validation test reports; and

z. Mesh product biocompatibility testing records;

6. All documents concerning your protocol or standard operating procedures (SOP) not listed in number 3 above for:

a. Your design and development department;

b. Your risk management department;

c. Your quality assurance department; and

d. Testing and Validation of TVT-S.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION NO. 2:12-md-02327** **MDL No. 2327**
	:	Judge Joseph R. Goodwin
This Document Applies To All Actions	:	

To: Christy D. Jones, Esq.
Butler, Snow, O'Mara Stevens & Cannada, PLLC
1020 Highland Colony Parkway, Suite 1400
Ridgeland, MS 39157
601-948-5711

PLAINTIFFS' CERTIFICATE OF SERVICE OF AMENDED NOTICE TO TAKE ORAL DEPOSITION OF DEFENDANT THROUGH DESIGNATED WITNESS REGARDING TVT-S

I hereby certify that on April 2. 2013, I served Plaintiff's Amended Notice to Take Oral Deposition of Defendant through Designated Witness regarding TVT-S via email and the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/Thomas P. Cartmell
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Plaintiffs' Co-Lead Counsel

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO ALL CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

AMENDED NOTICE TO TAKE ORAL DEPOSITION
OF DEFENDANT THROUGH DESIGNATED WITNESS REGARDING TVT-E

TO: Defendants ETHICON, INC., Johnson & Johnson, Inc., (hereinafter "Defendants") and its Attorneys of Record

Please take notice that pursuant Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of Defendants' corporate designee regarding TVT-E to begin on May 15, 2013, at 9:00 a.m., at the offices of Riker Danzig at One Speedwell Avenue in Morristown, New Jersey. The witness shall be prepared to testify concerning the subject matters identified in Exhibit "A", attached hereto. The witness shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day to day until the examination is completed.

DEFINITIONS

All definitions and rules of instructions set forth in Fed. R. Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device

industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

1. "Concerning" means referring to, describing, evidencing, or constituting. See LR. Civ. P. 26.2(c)(7).

2. "Defendants", "Ethicon, Inc.", "Johnson & Johnson Inc.", "you" or "your" refers to, without limitation, Ethicon, Inc., and Johnson & Johnson Inc., and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. "Document" is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR. Civ. P. 26.2(c)(2); *see also* Fed. R. Civ. P. 34(a).

4. "TVT-E" means the TVT-Exact device cleared by the FDA on or about March 16, 2010, which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).

5. "Relevant Time Period" means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold TVT-E to the present.

PLAINTIFFS' CO-LEAD COUNSEL

By: ____/s/Thomas P. Cartmell______________

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850-916-7449
Rbaggett@awkolaw.com
Plaintiffs' Co-Lead Counsel

EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge of and shall be able to testify concerning the following subject matters related to "TVT-E" defined in Paragraph 4 of Notice of Deposition:

I. DESIGN AND DEVELOPMENT OF MESH PRODCUTS

a. The Standard Operating Procedures (SOP) associated with design and development of TVT-E;

b. The complete design history file for TVT-E, including each component part of the file, the custodian responsible for the file and the maintenance of the file;

c. Members and procedures of the Product Development Team for TVT-E;

d. The Operating Procedures associated with Product Development Cycle;

e. The Design Output file, including the specifications of the TVT-E;

f. The user needs and design requirements for the TVT-E;

g. The Cadaver Lab evaluations for the TVT-E;

h. The specifics of all testing related to the TVT-E during the design and development stages, including but not limited to bench testing, porosity testing, particle loss, fraying, degradation, and leaching;

i. All project names of the TVT-E;

j. Design verification of the TVT-E;

k. Design validation of the TVT-E;

l. The Design Review, Process Qualification (PQ) and Design Transfer for the TVT-E;

m. The Product Device Design Safety Assessment (DDSA) and the policies and procedures related to these analyses;

n. Product Device Design Failure Modes Effects Analysis (dFMEA), Process Failure Modes Effects Analysis (pFMEA) and Application Failure Modes Effects Analysis (aFMEA);

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o. The Product Device Design Requirements Matrix;

p. The Product Device Qualitative and Quantitative Characteristics Worksheets, including but not limited to Hazard Worksheet and ranking tables;

q. The Clinical Validation Test Reports;Procedures for preparing and keeping Minutes and Agendas for Design Review Meetings;

r. As it relates to design control and validation, any and all discussions or documents related to whether or not to design, develop, coordinate, create, participate in and/or fund any clinical registries regarding your TVT-E;

s. Any patents related to the TVT-E and its predecessor mesh products;

t. The identity of and financial compensation paid to any consultants retained during the design and development of the TVT-E;

u. The monitoring, investigation and evaluation of post-marketing adverse event reports for your TVT-E for design issues;

v. The monitoring, evaluation and utilization of unpublished and/or published medical literature regarding your TVT-E for design issues;

w. As it relates to design control and validation, the investigation, evaluation and determination as to whether there is an association between the design of TVT-E and any adverse event experienced by patients who were provided your TVT-E;

x. The investigation, evaluation and determination as to whether there is a causal connection between the design of your TVT-E and any adverse event or injuries;

y. The substantive design and approval of package inserts, IFUs, and other labeling for your TVT-E (both U.S. and foreign), including the specific dates of use for each such items and any design changes thereto;

ii. The maintenance of Ethicon Inc.'s finances, budgets and expenditures with regard to design and development related to its TVT-E from the date first started developing its TVT-E until the present;

jj. The interaction and communication internally or with any outside consultants regarding the design specifications, including conformance to specifications of your TVT-E, from the date Ethicon, Inc. first started developing TVT-E until the present;

kk. As they relate to design control and validation, the manufacturing processes, including but not limited to heating/extrusion/annealing/cooling/gamma radiation/sterilization;

z. The identity of the individuals involved the defendants' original decision to design, develop and manufacture the TVT-E;

aa. All medical assessments of the TVT-E as it relates to the design control and validation process;

bb. The specifics of all clinical, preclinical, and medical testing related to the TVT-E during the design and development stages;

cc. Animal Testing Records for Biocompatibility as part of the design of the product;

dd. The evaluation of data and results of any pre-clinical studies, clinical trials and testing regarding your TVT-E;

ee. The development and coordination of any pre-clinical studies, clinical trials and design testing regarding your TVT-E;

EXHIBIT "B"

DOCUMENT REQUESTS

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.

2. Two exemplar products for all products listed in "TVT-E" definition above.

3. Prototype meshes and tissue samples/pathology/histopathology slides of all pathology testing on TVT-E.

4. All documents concerning corporate, departmental, and employee organizational charts for your design and development department, product development or product cycle teams.

5. The following documents for the design and development of TVT-E, including but not limited to:

   a. The Clinical Expert reports;

   b. Each version of the Device Design Safety Assessment (DDSA's); Each version of the Design Failure Modes Effects Analysis (dFMEAs), Process Failure Modes Effects Analysis (pFMEAs), Application Failure Modes Effects Analysis (aFMEA);

   c. Operating Procedures for Failure Modes and Effects Analysis;

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   e. Design history files;

   f. Design and specifications of equipment used in the production of TVT-E;

   g. Design and specifications of packaging used in the production of TVT-E;

   h. Specifications regarding sanitization and sterilization of TVT-E, plant facilities and plant equipment;

   i. Mesh Specifications;

   j. Franchise procedure for medical device risk management plan;

   k. Company procedure for medical device risk management plan;

   l. Work Instruction for device risk management;

   m. The Franchise procedure for the control and disposition of nonconforming product;

n. All company policies and procedures that apply to or relate to the Design History File;

o. The Franchise Procedure for Corrective and Preventative Action (CAPA) as well as any other company policies and procedures related to CAPAs;

p. Risk management plans and reports for TVT-E;

q. Members of product development team(s);

r. Operating procedures associated with a product development cycle;

s. TVT-E quality manual;

t. TVT-E quality plan;

u. Management responsibilities under a quality system;

v. Mesh product design review, design verification, process qualification and design transfer;

w. Mesh product device design requirements matrix;

x. Mesh product qualitative and quantitative characteristics worksheets, including but not omitted to hazard worksheet raking tables;

y. Mesh product validation test reports; and

z. Mesh product biocompatibility testing records;

6. All documents concerning your protocol or standard operating procedures (SOP) not listed in number 3 above for:

a. Your design and development department;

b. Your risk management department;

c. Your quality assurance department; and

d. Testing and Validation of TVT-E.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION NO. 2:12-md-02327** **MDL No. 2327**
This Document Applies To All Actions	:	Judge Joseph R. Goodwin

To: Christy D. Jones, Esq.
Butler, Snow, O'Mara Stevens & Cannada, PLLC
1020 Highland Colony Parkway, Suite 1400
Ridgeland, MS 39157
601-948-5711

PLAINTIFFS' CERTIFICATE OF SERVICE OF AMENDED NOTICE TO TAKE ORAL DEPOSITION OF DEFENDANT THROUGH DESIGNATED WITNESS REGARDING TVT-E

I hereby certify that on April 2, 2013, I served Plaintiff's Amended Notice to Take Oral Deposition of Defendant through Designated Witness regarding TVT-E via email and the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/Thomas P. Cartmell

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850-916-7449
Rbaggett@awkolaw.com
Plaintiffs' Co-Lead Counsel

CERTIFICATION OF SERVICE

I certify that on this date I caused the attached Responses & Objections to Plaintiffs' Notices of 30(b)(6) Deposition of Defendants Johnson & Johnson, Ethicon, Inc. and Ethicon Women's Health & Urology to be served by LexisNexis File & Serve upon all counsel of record, and by e-mail upon Plaintiffs' Co-Liaison Counsel in New Jersey and Coordinating Co-Lead Counsel in the MDL:

Adam M. Slater, Esq.
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Diana Katz Gerstel

Dated: April 15, 2013

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